FDA 510(k) Premarket Notification

K153358 Standard Clamp

CLEARED

May 2, 2016
164 days to decision

K153358 · Product code: **GDJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k153358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Surgical, General & Plastic Surgery (GDJ)
Date received	Nov 20, 2015
Decision date	May 2, 2016
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Standard Bariatrics**
Location	Cincinnati, OH, US
Contact	ALISON SATHE
510(k) history	10 submissions · 10 cleared · 2016-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k153358/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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